

EXHIBIT C

**TO THE DECLARATION
OF DIANE C. RAGOSA, ESQ. IN
SUPPORT OF DEFENDANTS' MOTION FOR
PARTIAL SUMMARY JUDGMENT OF ANTICIPATION
OF CLAIMS 1, 2 AND 5 OF U.S. PATENT NO. 7,662,787**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/745,019	05/07/2007	Travis Mickle	20342/1202521-US3	1031
7278	7590	11/12/2008	EXAMINER	
DARBY & DARBY P.C.			AUDET, MAURY A	
P.O. BOX 770			ART UNIT	
Church Street Station			PAPER NUMBER	
New York, NY 10008-0770			1654	
			MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

11/745,019

Applicant(s)

MICKLE ET AL.

Examiner

MAURY AUDET

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/7/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The present application is a division of U.S. S.N. 10/857,619 (now US 7223735), examined and allowed by the present Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over NL 6414901 (Hoffmann-La Roche & Co.; French version 1421130, cited in the IDS of 02/14/2005 of Parent US S.N. 10/857,619) [SEE IDS/PARENT FOR COPY].

NL 6414901 expressly teach L-lysine-d-amphetamine (page 11, compound 9). It is noted that this compound contains an N alpha group protected with a protecting group (well known protecting group tosyl; thus the present rejection is made under 35 USC section 103 as an obvious variant). However, NL 6414901 also expressly teach unprotected Lys-Amp. compounds (page 11, compound 8, though not specifically the L-lys and/or d-Amp. form). NL 6414901 also teach salt forms of Lys-Amp. (see again page 11, compound 8, oxalate salt). Additionally, NL 6414901 teach that the compounds described therein, such as L-Lys-d-amp., are to be used in pharmaceutical compositions (claim 6), in tablet form suitable for oral administration; with various additives such as calcium carbonate (page 12, Examples), in an amount sufficient to provide a pharmacologically effective amount to treat a patient in need of amphetamine (page

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12, Examples; entire document) and in an amount sufficient to provide a therapeutic bioequivalent Area Under the Curve (AUC) when compared to amphetamine alone, but in an amount sufficient to provide a Cmax which results in euphoria (page 12, Examples; based on the same compound (amp.) bearing the same properties once enzymatically/chemically cleaved from the protective amino acid Lys; absent evidence to the contrary that 20-50 mg doses of such compounds would not render the same effect).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a unprotected L-lysine-d-amphetamine in the compositions of NL 6414901, because NL 6414901 advantageously teach the use of either protected or unprotected Lys-Amp. compounds, and the selection of making/using unprotected L-lysine-d-amphetamine is merely a matter of routine optimization by one of ordinary skill in the art, and a factor for consideration if needed to prevent the reactive N alpha or N epsilon groups from reacting with other compounds in solution (or unprotecting if not of concern), depending on the desired effects.

Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over NL 6414901 (Hoffmann-La Roche & Co.; French version 1421130, cited in the IDS of 02/14/2005) in view of Eptsein et al. (US 2002/0115725 A1).

NL 6414901 is discussed above. Although NL 6414901 teach Lys-Amp. salts such as oxalate (page 11, compound 8); the reference does not expressly teach the use of the salt forms of mesylate or HCl (Applicant's claims 41-42, and 44-45).

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Epstein et al. teach the use of amphetamine salts, such as oxalate, mesylate, and HCl, in composition for such disorders as ADHD (para. 205, 358, claim 24-26).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use any of oxalate, mesylate or HCl salts forms of unprotected L-lysine-d-amphetamine in the compositions of NL 6414901, because Epstein et al. teach that the choice of using salts such as oxalate, mesylate, or HCl as the salt form of amphetamines is well known in the art (for use in compositions for such disorders as ADHD) and is merely a matter of routine optimization by one of ordinary skill in the art; and NL 6414901 advantageously teaches the use of the oxalate salt form of Lys-Amp. compounds, thus rendering the salt selection merely a matter of routine optimization by one of ordinary skill in the art. As discussed above, NL 6414901 also advantageously teach either protected or unprotected Lys-Amp. compounds, and the selection of making/using unprotected L-lysine-d-amphetamine is merely a matter of routine optimization by one of ordinary skill in the art, and a factor for consideration if needed to prevent the reactive N alpha or N epsilon groups from reacting with other compounds in solution (or unprotecting if not of concern), clearly providing motivation for salt forms of the protected or unprotected forms as well, depending on the desired effects.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 3-4, and 12 of U.S. Patent No. 7223735 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the additive may be "a pharmaceutically acceptable salt", the original restriction requirement is moot, as Applicant has wholly included the Markush group of the presently claimed invention in his US 7223735 B2.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960.

The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 10/1/2008

/Maury Audet/
Examiner, Art Unit 1654